

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

United States of America <i>ex rel.</i>	:	
Marc Young, Jeremy W. Briggs, and	:	
Joseph B. Lawrence,	:	
	:	
<i>Plaintiffs and</i>	:	District Judge Susan J. Dlott
<i>Relators</i>	:	
	:	
v.	:	
	:	
Golden State Medical Supply, Inc.	:	Case No. 1:17-cv-373
	:	
Lucid Pharma LLC <i>et al.</i> ,	:	Case No. 1:16-cv-969
	:	
Exelan Pharmaceuticals, Inc.,	:	Case No. 1:16-cv-1045
	:	
AvKARE, INC.	:	Case No. 1:17-cv-421
	:	
Mylan Pharmaceuticals, Inc.	:	Case No. 1:17-cv-529
	:	
<i>Defendants</i>	:	

**JOINT MOTION TO STAY CIVIL PROCEEDINGS**

Plaintiffs/Relators Marc Young, Jeremy W. Briggs, and Joseph B. Lawrence (“Relators”) and named Defendants, Golden State Medical Supply, Inc., Acetris Health, LLC, Exelan Pharmaceuticals, Inc., AvKARE, INC. and Mylan Pharmaceuticals, Inc., (collectively “the Parties”), all jointly move this Court to stay the proceedings in the following actions (collectively “the Proceedings”):

- *United States ex rel. Young et al. v. Golden State Medical Supply, Inc.*, 1:17-cv-00373-SJD
- *United States ex rel. Young et al. v. Lucid Pharma LLC et al.*, 1:16-cv-00969-SJD
- *United States ex rel. Briggs et al. v. Exelan Pharmaceuticals Inc.*, 1:16-cv-01045-SJD
- *United States ex rel. Young et al. v. AvKARE, Inc.*, 1:17-cv-00421-SJD
- *United States ex rel. Briggs et al. v. Mylan Pharmaceuticals Inc.*, 1:17-cv-00529-SJD

The Parties seek to stay the Proceedings pending both a decision by the United States Court of Appeals for the Federal Circuit in *Acetris Health, LLC v. United States*, No. 18-2399 (Fed. Cir. Sept. 20, 2018), and a decision in the trial proceedings in the Court of International Trade in *Acetris Health, LLC v. United States, Consol. Court No. 18-00040*.<sup>1</sup> The Moving Parties in the Proceedings agree that common legal issues are raised in these cases and decisions in these actions may impact this Court's potential consideration of certain of the Proceedings' common legal issues and defenses under the False Claims Act, 31 U.S.C. § 3729 *et seq.*

This Court has the inherent power to stay proceedings. *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). Staying this action will promote judicial efficiency and will serve the public interest because the Federal Circuit's decision in the pending appeal involving Acetris Health, LLC ("Acetris") and the pending *Acetris* case before the Court of International Trade may address the interpretations of Trade Agreements regulations and related statutes underlying Relators' legal theory.

No party will be unduly prejudiced by this stay while the Federal Circuit and the Court of International Trade consider certain of the same legal issues that are involved in these Proceedings. A Memorandum of Law in support of this request is incorporated herein.

**WHEREFORE**, the Moving Parties in the Proceedings, Plaintiffs/Relators Marc Young, Jeremy W. Briggs, and Joseph B. Lawrence and Defendants, Golden State Medical Supply, Inc., Acetris Health, Exelan Pharmaceuticals, Inc., AvKARE, INC. and Mylan Pharmaceuticals, Inc., pray that this Honorable Court:

A. Grant the Joint Motion to Stay Civil Proceedings; and

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<sup>1</sup> References to "Parties" or to "Moving Parties" do not include Defendant Lucid Pharm LLC who is also a named defendant in *U.S. ex rel. Young et al v. Lucid Pharma LLC et al.*, 1:16-cv-00969-SJD. See *infra*, Memorandum at n.1.

B. Enter an Order in each action staying the proceeding pending further notice by the Parties that the proceedings in *Acetris Health, LLC v. United States*, No. 18-2399 (Fed. Cir. Sept. 20, 2018) and *Acetris Health, LLC v. United States*, Consol. Court No. 18-00040 (Court of International Trade) each have a decision; and,

C. Award such other and further relief as the nature of this case may require.

Respectfully submitted,

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Mylan Pharmaceuticals, Inc.	:	Case No. 1:17-cv-529
	:	
<i>Defendants</i>	:	

**MEMORANDUM OF LAW IN SUPPORT OF  
JOINT MOTION TO STAY CIVIL PROCEEDINGS**

**I. Background For Joint Stay Request.**

Between September 30, 2016 and August 10, 2017, Plaintiffs/Relators initiated five separate False Claims Act actions in this Court under the private citizen provisions of the civil False Claims Act, 31 U.S.C. § 3730(b), against six pharmaceutical companies, the defendants in the actions *United States ex rel. Young et al. v. Golden State Medical Supply, Inc.*, 1:17-cv-00373-SJD, *United States ex rel. Young et al. v. Lucid Pharma LLC et al.*, 1:16-cv-00969-SJD, *United States ex rel. Briggs et al. v. Exelan Pharmaceuticals Inc.*, 1:16-cv-01045-SJD, *United States ex*

*rel. Young et al v. AvKARE, Inc.*, 1:17-cv-00421-SJD, and *United States ex rel. Briggs et al. v. Mylan Pharmaceuticals Inc.*, 1:17-cv-00529-SJD.<sup>1</sup>

The complaints all commonly allege that the Defendants knowingly violated the terms of their Government contracts by selling to the United States pharmaceutical products in violation of the Trade Agreements Act (“TAA”).<sup>2</sup> All five actions assert the same legal theory: namely, that the Defendant parties violated the False Claims Act in the sale of pharmaceutical products to the United States governed by Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS). Plaintiffs contend that the certifications and/or claims for payment are false because the products have been sold in violation of the TAA by falsely certifying and/or representing that the product was U.S.-made or an approved designated country end product. Defendants deny these allegations. While six companies are involved in the Proceedings, the legal issues have broad interest in the health industry sector.

The Department of Justice, on behalf of the United States, reviewed the allegations and declined to intervene in these Proceedings. *See* 1:17-cv-00373-SJD at Dkt. 25; 1:16-cv-00969-SJD at Dkt. 27; 1:16-cv-01045-SJD at Dkt. 27; 1:17-cv-00421-SJD at Dkt. 20; and 1:17-cv-00529-SJD at Dkt. 19. All named Defendants except Lucid executed waivers of service. Their responses to the Complaints are due generally in mid-January but no responses have been filed to date.

All Defendants in the Proceedings (other than Lucid whose counsel has not yet entered an appearance) deny the allegations asserted and will be filing motions to dismiss pursuant to Fed. R.

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<sup>1</sup> In addition to the five Defendants in the five lawsuits respectively identified in the first sentence of this Joint Motion, Plaintiffs/Relators also named a sixth pharmaceutical company, Lucid Pharma LLC (“Lucid”), as a Defendant in Case No. 1:16-cv-969 as Lucid was the predecessor-in-interest to the other Defendant named in that action. On December 11, 2018, Lucid was served with Plaintiffs/Relators’ Second Amended Complaint through personal service on its principal equity owner, executive officer, and/or member, Vimal Kavuru. *See* 1:16-cv-00969-SJD at Dkt.33. Lucid’s counsel has represented to Relators’ counsel that Lucid agrees to the stay and that counsel for Lucid will be entering an appearance next week and will be filing a separate joinder in this Motion to Stay.

<sup>2</sup> The False Claims Act (sometimes referred to as the “FCA”) requires that Relators initially file their complaint under seal and the complaint may be served after an intervention decision by the United States. *See* 31 U.S.C. § 3730(b)(2).

Civ. P. 9(b) and 12(b)(6) on several independent grounds. All Parties recognize, however, that parallel to the Proceedings in this District are two separate judicial proceedings currently pending before the Federal Circuit Court of Appeals and the Court of International Trade that may address the same legal issues presented in Relators' Complaints and, therefore, may provide important guidance to this Court in evaluating, if necessary, the applicability of the FAR and DFARS regulations and related statutes in dispute.

In essence, the Proceedings involve a legal dispute regarding the legal meaning of the standard language included in the "Trade Agreements Clause" of Defendants' contracts with the United States. Under the Trade Agreements Clause, a product may be purchased by the U.S. government, without a non-availability determination, if it is (a) a U.S.-made end product, or (b) a designated country end product. Specifically at issue in the Proceedings is whether each generic drug product offered by Defendants for sale to the Government is a "U.S.-made end product" or a "designated country end product."

The Parties seek to stay this action because the meaning of the Trade Agreements Clause in standard form government contracts is currently being litigated by Acetris Health, LLC ("Acetris") and the United States in the Federal Circuit. The United States recently appealed the Court of Federal Claims' decision in *Acetris Health, LLC v. United States*. 138 Fed. Cl. 579 (Fed. Cl. 2018) (finding that Acetris' products could be U.S.-made end products for the purposes of the Trade Agreements Clause where they were manufactured in the U.S., regardless of the origin of the components or whether those components were substantially transformed in the U.S. under the TAA). This issue of what constitutes U.S.-made end products is a threshold legal issue for the False Claims Act theory of liability in the Proceedings. The United States has already filed its

appellate brief and that appeal is expected to be heard in 2019. *See Acetris Health, LLC v. United States*, appeal docketed, No. 18-2399 (Fed. Cir. Sept. 20, 2018) at Dkt. 19.

Similar aspects of interpretation of the Trade Agreements Clause are also at issue in the Court of International Trade in *Acetris Health v. United States*, No. 18-cv-00040 (Ct. Int'l Trade), scheduled for trial in 2019, where Acetris has challenged the U.S. Customs and Border Protection (CBP) determination that its products were not U.S.-made end products. Both of these pending actions may address a legal standard for determining country of origin of pharmaceutical products sold in the U.S. and, therefore, may have relevance for this Court's assessment of the applicable regulatory structure at the heart of the alleged False Claims Act violations.

## **II. A Stay is Appropriate in this Matter.**

United States Supreme Court precedent recognizes that district courts have the discretion to stay pending proceedings: “[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its own docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). Courts in this district have broad discretion to stay a matter “pending resolution of independent proceedings which bear upon the case at hand.” *Unroe v. Vilsack*, 2012 WL 3527219, at \*1 (S.D. Ohio Aug. 14, 2012) (internal citations omitted). A stay may be warranted where there is “a concurrently pending federal action (either because the claim arises from the same nucleus of facts or because the pending action would resolve a controlling point of law).” *SST Global Tech., LLC v. Chapman*, 270 F. Supp. 2d 444, 455 (S.D.N.Y. 2003) (emphasis omitted). For a stay to issue, the parties and the issues do not have to be identical (*see Landis*, 299 U.S. at 254), instead “the ‘crucial inquiry’ is one of substantial overlap of the issues[.]” *Wolf Designs, Inc. v. Donald McEvoy Ltd.*, 341 F.Supp.2d 639, 643 (N.D. Tex. 2004) (citation omitted). In this matter, all parties in the Proceedings agree that a stay is warranted. No public interest will be harmed and no party

asserts prejudice from a stay. Further, judicial economy is served by staying active litigation in the unique circumstances of highly relevant proceedings in other courts of special jurisdiction that may adjudicate legal issues that may impact the scope of these Proceedings. *See, e.g., Ramcharitar v. Procter & Gamble Co.*, 2016 WL 796129, at \*1 (S.D. Ohio Mar. 1, 2016); *Canter v. Calderhead, Lockenmeyer & Peschke Law Office*, 2014 WL 64155, at \*1 (S.D. Ohio Jan. 8, 2014). While Defendants will assert defenses separate and apart from the legal interpretation issues in the *Acetris* cases, a stay will give federal courts with subject-matter expertise time to review and interpret regulations and statutes that may be relevant to Relators' assertion of False Claims Act liability.

### **III. A Stay Would Promote Judicial Economy and Efficiency.**

Judicial economy and efficiency will also be promoted by a stay. A stay is appropriate where there are ongoing parallel federal proceedings that may clarify the issues that have been raised in another lawsuit. *See Ramcharitar*, 2016 WL 796129 at \*2. While not binding on this Court, the decisions of the courts that specialize in this narrow area of the law may be highly informative to this Court and may streamline the legal issues in dispute as well as narrow the scope of discovery. A stay may also avoid the risk of inconsistent decisions. *See, e.g., Canter*, 2014 WL 64155 at \*2 (judicial economy supports granting motion for stay where many of the legal and factual issues raised will likely be resolved in other pending action). As the Supreme Court has recognized, “[t]o permit a situation in which two cases involving precisely the same issues are simultaneously pending in different District Courts leads to the wastefulness of time, energy and money.” *Continental Grain Co. v. Barge FBL-585*, 364 U.S. 19, 26 (1960) (discussing venue transfer provision provided in 28 U.S.C. § 1404(a)). Judicial resources, accordingly, may be preserved if the Proceedings are stayed.

In this district, the judicial economy that results where a stay avoids duplicative litigation has also been recognized as beneficial to the public interest. *Gill v. Convergent Outsourcing, Inc.*, No. 16-cv-01035, 2017 U.S. Dist. LEXIS 92286 \*7-8 (S.D. Ohio) (Deavers, M.J.).

#### **IV. A Stay Would Not Prejudice the Parties.**

All Parties agree that staying this matter is not prejudicial and will save resources, promote judicial economy and provide the Court with guidance that may affect future decisions. Unlike the Proceedings, the Federal Circuit and Court of International Trade cases have already advanced through active litigation with one instructive decision on appeal before the Federal Circuit. In contrast, because of the mandatory seal period, motions and discovery have not yet begun in the Proceedings. Because the same issues of legal interpretation involved in these other actions may define the scope of the Proceedings, a stay is an appropriate exercise of discretion. It is understood and agreed by the Parties that all rights and defenses related to the Proceedings are preserved and not waived during the pendency of any stay. In the event the stay is not granted for any reason, all Parties agree that motions to dismiss or transfer or other responsive pleadings will be filed within 30 days of this Court's order denying the request for stay.

#### **Conclusion**

For the reasons identified to the Court, the Parties respectfully request that the Court stay the Proceedings pending both a decision by the Federal Circuit in the appeal now pending in *Acetris Health, LLC v. United States*, No. 18-433C (Fed. Cl.), *appeal docketed*, No. 18-2399 (Fed. Cir. Sept. 20, 2018) and a decision in the related trial proceedings currently pending in that Circuit's subordinate court in *Acetris Health, LLC v. United States*, Consol. Court No. 18-00040 (Ct. Int'l Trade).

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I hereby certify that on January 11, 2019, the foregoing document was electronically served upon all counsel of record registered through the CM/ECF system and was served via electronic mail upon the following:

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